UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

JAMES LANDMESSER, JR. A resident of Silver Spring, Maryland Plaintiff, vs. BAYER CORPORATION, an Indiana corporation, Successor to CUTTER BIOLOGICAL, a California Corporation; BAXTER HEALTHCARE CORPORATION, a Delaware corporation, and its HYLAND DIVISION; ARMOUR PHARMACEUTICAL COMPANY, INC., a Delaware corporation and ALPHA THERAPEUTIC CORPORATION, a California corporation, Defendants.	:	Case No. 1:08-cv-03872 (Related to MDL No. 986 JFG) District Judge John F. Grady

DEFENDANT BAXTER HEALTHCARE CORPORATION'S ANSWER TO PLAINTIFF'S COMPLAINT, AFFIRMATIVE DEFENSES AND DEMAND FOR JURY TRIAL

General Denial

Baxter Healthcare Corporation ("Baxter"), improperly identified in the Complaint and sued as Baxter Healthcare Corporation and its Hyland Division, by its undersigned attorneys, denies that it is liable in any way to Plaintiff based on the allegations in the Complaint. Baxter Healthcare Corporation states that to the extent this Complaint contains allegations directed to any alleged entity other than Baxter Healthcare Corporation, either explicitly or otherwise, no answer is required by Baxter Healthcare Corporation. No response by Baxter Healthcare Corporation herein shall be deemed a response to allegations directed to any other alleged entity. All references to "Baxter" in the Complaint shall be deemed to refer solely to Baxter Healthcare

Corporation for purposes of this Answer. And, to the extent Baxter responds to allegations regarding Factor VIII and Factor IX concentrates, Baxter's responses shall be deemed to apply only to its Factor VIII and Factor IX concentrates and not to therapies processed by any other entity. Specifically, Baxter answers Plaintiff's Complaint as follows:

I. ANSWER TO PLAINTIFF'S INTRODUCTION

1. Defendants manufactured blood products known as "Factor VIII" and "Factor IX" for the treatment of hemophilia, and sold these products to people with hemophilia in the United States and worldwide, despite knowledge that the products were manufactured from sick, high-risk donors and/or known to be contaminated with the virus that causes Non-A, Non-B Hepatitis (now known as "Hepatitis C" or "HCV"). Defendants knowingly declined to timely pursue or adopt treatment and manufacturing practices that would have prevented the infection of Plaintiff with HCV, as described in more detail below. Defendants also continued selling old stocks of products they knew to be contaminated with HCV even after they or others had introduced safer products. Plaintiff is a person with hemophilia who contracted HCV through use of Defendants' contaminated products. This complaint describes the factual predicate for Plaintiff's infection: a pattern of foot-dragging, denial, and obfuscation by the pharmaceutical companies on whom his health and well-being depended.

PARAGRAPH NO. 1 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter admits only that it processed human plasma into Factor VIII and Factor IX concentrate used for the treatment of hemophilia. Baxter specifically denies that it engaged in any misconduct, denies that it "manufactured" Factor VIII or Factor IX, and denies that Factor VIII or Factor IX concentrates are blood "products." The remaining factual allegations directed to Baxter, if any, are denied.

2. Defendants manufactured HCV-contaminated blood factor products using human plasma taken from thousands of paid donors, including populations then known to be at high risk of carrying blood-borne diseases, such as urban homosexuals, prisoners, and intravenous drug users. Defendants intentionally recruited urban homosexuals who had a history of viral hepatitis as plasma donors, despite regulations prohibiting the use of such donors and despite knowledge that the virus that causes HCV was a blood-borne disease prevalent in such populations.

Defendants continued using plasma taken from high-risk prison donors, even after promising the FDA that they would cease doing so. Through their trade associations, Defendants actively conspired to conceal these practices and to substantially delay product recalls and implementation of safety measures.

PARAGRAPH NO. 2 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter admits only that it processed factor concentrates from pooled plasma. Baxter denies that it "manufactured" Factor VIII or Factor IX concentrates, or that Factor VIII or Factor IX concentrates are blood "products." By way of further answer, Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge. The remaining factual allegations directed to Baxter, if any, are denied.

3. Defendants failed to fully and completely disclose the known risks of their products, including the risk of HCV; failed to implement readily available screening tests that would have prevented HCV by excluding contaminated plasma; failed to use available methods of treating plasma to kill viruses, including treatment with solvents and/or detergents; and concealed and affirmatively misrepresented the extent of the health dangers of the diseases caused by the products. Defendants also continued to sell old stocks of product that had not been treated even after introducing a safer treated product, including stocks that Defendants knew or had reason to know were made from pooled blood contaminated with HCV.

PARAGRAPH NO. 3 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter denies that Factor VIII or Factor IX concentrates are "products." The remaining factual allegations directed to Baxter, if any, are denied.

4. Defendants' efforts to maximize profits came at the expense of the health and lives of thousands of people with hemophilia in the United States and worldwide who were needlessly infected with HCV, including JAMES LANDMESSER, JR.

PARAGRAPH NO. 4 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter states that hepatitis transmission was a known risk associated with the use of factor concentrate and all Baxter factor concentrates carried an FDA approved hepatitis warning. The remaining factual allegations directed to Baxter, if any, are denied.

II. ANSWER TO ALLEGATIONS REGARDING JURISDICTION AND VENUE

5. Plaintiff alleges an amount in controversy in excess of $75,000, exclusive of interest and costs. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants.

PARAGRAPH NO. 5 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter and therefore no response is required.

6. Plaintiff resides in the State of Maryland and a significant portion of the conduct relevant to the subject matter of this case took place within this jurisdiction.

PARAGRAPH NO. 6 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

7. Plaintiff is informed and believes and on such information and belief alleges that Defendants do business within the State of Maryland and intended their products, put into the stream of commerce, to be purchased and used in the State of Maryland, giving this State significant contacts to the claims asserted by Plaintiff.

PARAGRAPH NO. 7 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter and therefore no response is required.

To the extent that this paragraph includes factual allegations directed to Baxter, Baxter admits that it is licensed to do business in multiple states, including Maryland. The remaining factual allegations directed to Baxter, if any, are denied.

III. ANSWER TO ALLEGATIONS REGARDING PARTIES

8. Plaintiff JAMES LANDMESSER, JR. is a resident of Silver Spring, Maryland, who has hemophilia. Plaintiff has already provided Defendant with a confidential Preliminary Patient Profile Form ("PPPF"), with beginning Bates number L-PPF 005992. The PPPF contains substantial additional information regarding Plaintiff's claim.

9. Plaintiff was infected with HCV and experienced physical and emotional harm as a direct and proximate result of his use of Defendants' blood products.

PARAGRAPH NOS. 8-9 ANSWER: To the extent that the allegations of these paragraphs constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter is without knowledge or information sufficient to form a belief as to the truth of the alleged facts relating to Plaintiff's citizenship, country of residence, hemophilia treatments, medical condition, state of mind or other personal information, and therefore denies them. Baxter denies all remaining factual allegations directed to Baxter.

10. Plaintiff would not have chosen to be treated with Defendants' blood products, nor would have his guardians, had they known of or been informed by Defendants of the true risks of using those products or the nature of the sources of the products.

PARAGRAPH NO. 10 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

11. Defendant CUTTER BIOLOGICAL ("CUTTER"), the predecessor of Miles, Inc., and Defendant BAYER, was a California corporation headquartered in Berkeley, California at all pertinent times. At all pertinent times CUTTER and its successors Miles, Inc. and BAYER regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of factor concentrates produced from such plasma, to which Plaintiff was exposed and which contributed directly or indirectly to Plaintiff's infection with HCV.

12. Defendant BAYER CORPORATION ("BAYER"), formerly Miles, Inc., is and was an Indiana corporation, authorized to do business in all 50 states and the District of Columbia. Miles, Inc. had its principal place of business operation in Elkhart, Indiana, while its successor BAYER has its principal place of business in Pennsylvania, with offices located at 100 BAYER Road, Pittsburgh, Pennsylvania 15205. At all pertinent times BAYER and its predecessors Miles, Inc., and CUTTER regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of factor concentrates produced from such plasma, to which Plaintiff was exposed and which contributed directly or indirectly to Plaintiff's infection with HCV.

PARAGRAPH NOS. 11-12 ANSWER: The allegations of these paragraphs are directed to parties other than Baxter and therefore no response is required.

13. Defendant BAXTER HEALTHCARE CORPORATION ("BAXTER") is a Delaware corporation, authorized to do business in all 50 states and the District of Columbia, with its principal place of business in Illinois, with offices located at One Baxter Parkway, Deerfield, Illinois 60015. At all times pertinent, Defendant BAXTER, and/or its HYLAND DIVISION, had its main manufacturing plant in Glendale, California. At all times pertinent, Defendant BAXTER, and/or its HYLAND DIVISION, and/or its wholly owned subsidiaries Travenol Laboratories, regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sale and distribution of FACTOR CONCENTRATE products produced from such plasma, to which Plaintiff was exposed and which contributed directly or indirectly to Plaintiff's infection with HCV.

PARAGRAPH NO. 13 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or relate to parties other than Baxter, no response is required. To the extent that this paragraph includes factual allegations directed to Baxter, Baxter admits that it is a Delaware corporation, with its principal place of business in Deerfield, Illinois, and that it is licensed to do business in multiple states. Baxter further admits that it currently maintains a processing facility in Los Angeles, California. Baxter further admits that it has,

through its Hyland Division, been engaged in collecting plasma and processing and distributing Factor VIII and Factor IX concentrates. The remaining factual allegations directed to Baxter, if any, are denied.

14. Defendant ARMOUR PHARMACEUTICAL COMPANY, INC. ("ARMOUR") is a Delaware corporation, with its principal place of business in Pennsylvania, with offices located at 500 Arcola Road, P.O. Box 1200, Collegeville, Pennsylvania, 19426-0107. At all times pertinent, ARMOUR regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of factor concentrate products produced from such plasma, to which Plaintiff was exposed and which contributed directly or indirectly to Plaintiff's infection with HCV.

15. Defendant ALPHA THERAPEUTIC CORPORATION ("ALPHA") is a California corporation, with its principal place of business in California, with offices at 5555 Valley Boulevard, Los Angeles, California 90032. At all times pertinent, Defendant has been regularly and systematically engaged in the harvesting and collection of human plasma, and the processing, manufacturing, marketing, sale and distribution of factor concentrate products produced from such plasma to which Plaintiff was exposed and which contributed directly or indirectly to Plaintiff's infection with HCV.

PARAGRAPH NOS. 14-15 ANSWER: The allegations of these paragraphs are directed to parties other than Baxter and therefore no response is required.

16. Defendants CUTTER, BAXTER, ARMOUR and ALPHA (hereinafter collectively referred to as "Defendants"), acting on behalf of themselves and/or their predecessor and/or successor corporations, collected, harvested and/or processed human plasma and/or manufactured, marketed, sold and distributed factor concentrate products that were contaminated with HCV. In the alternative, one or more of said Defendants participated in the collection, harvesting and/or processing of human plasma, and/or the manufacturing, marketing, distribution and sale of factor concentrate products that were contaminated with HCV; or assumed or became responsible for, the liabilities of the Defendants and their predecessor or successor corporations who did participate in the collection, harvesting and/or processing of human plasma, and/or the manufacturing, marketing, distribution or sale of factor concentrate products that were contaminated with HCV, without limitation thereto.

PARAGRAPH NO. 16 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. Baxter admits that it is, and has in the past been engaged in collecting plasma and

processing and distributing Factor VIII and Factor IX concentrates. The remaining factual allegations directed to Baxter, if any, are denied.

17. At all times herein mentioned, Defendants were fully informed of the actions of their agents and employees, and thereafter no officer, director or managing agent of Defendants repudiated those actions, which failure to repudiate constituted adoption and approval of said actions, and Defendants thereby ratified those actions.

PARAGRAPH NO. 17 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. Baxter is without knowledge or information sufficient to form a belief as to the vague and ambiguous term "actions," and therefore allegations based thereon are denied.

IV. ANSWER TO PLAINTIFF'S "FACTUAL ALLEGATIONS" APPLICABLE TO ALL CLAIMS

A. Answer to Allegations Regarding Hemophilia and Its Treatment

18. Hemophilia is an inherited condition that causes uncontrolled hemorrhaging or bleeding. Hemophilia results from a deficiency of blood components essential for coagulation. The most common form of the disease is hemophilia A, characterized by a lack of a blood protein known as Factor VIII, which affects approximately one in 10,000 males. Factor VIII is commonly called "AHF" or anti-hemophilic factor. Hemophilia B is characterized by absence of another blood, protein, known as Factor IX, affecting about one in 40,000 males. Plaintiff JAMES LANDMESSER, JR. has severe hemophilia A.

PARAGRAPH NO. 18 ANSWER: Baxter admits that hemophilia is an inherited hemorrhagic condition, the circumstances of which vary from individual to individual. Baxter is without knowledge or information sufficient to form a belief with respect to the allegations regarding Plaintiff's medical condition and therefore denies them. This paragraph does not state allegations directed to Baxter, but rather recites medical facts and information. Baxter denies the statements herein to the extent they are inconsistent with the current state of medical and scientific knowledge.

19. The treatment of hemophilia involves intravenous introduction, called infusion, of the missing blood proteins required to stop bleeding. The two most prevalent forms of such treatment are cryoprecipitate and factor concentrates. Factor concentrates are the products made by Defendants in this action. Cryoprecipitate is made by freezing plasma, the fluid component of circulating blood in which various proteins, including Factor VIII and Factor IX, are contained; thawing the frozen plasma; and isolating Factor VIII from the plasma through centrifugal concentration. Cryoprecipitate is an effective therapeutic agent for patients with hemophilia A. Hemophilia B has been effectively treated with the use of fresh frozen plasma containing Factor IX. Cryoprecipitate and fresh frozen plasma are made from small numbers of donors, who are generally unpaid volunteers.

PARAGRAPH NO. 19 ANSWER: Baxter admits that hemophilia is an inherited hemorrhagic condition, the circumstances of which vary from individual to individual. Baxter further admits that it does process and has in the past processed therapies known as factor concentrates. Baxter specifically denies that Factor VIII or Factor IX concentrates are "products." This paragraph does not state allegations directed to Baxter, but rather recites medical facts and information. Baxter denies the statements herein to the extent they are inconsistent with the current state of medical and scientific knowledge and/or are inconsistent with the instructions for use which accompany particular therapies.

20. In the late 1960s to early 1970s, Defendants began to market factor concentrates, which contained Factor VIII and Factor IX in higher concentrations than had been available in either cryoprecipitate or fresh-frozen plasma. To produce factor concentrates, Defendants mixed pools of plasma from five to over twenty thousand donors at a time, a large percentage of which were paid donors. These large pools were then subjected to processes to concentrate Factors VIII and IX.

PARAGRAPH NO. 20 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required from Baxter. Baxter admits only that it processes and distributes factor concentrates according to its own proprietary methods, from pooled plasma collected primarily from paid donors. The availability of factor concentrate therapies in the late 1960's and/or early 1970's

marked a huge advance in the treatment of hemophilia. The remaining factual allegations directed to Baxter, if any, are denied.

B. Answer to Allegations Regarding Failure to Disclose or Warn

21. Shortly after the initial commercial marketing of Factor VIII and IX concentrates in the late 1960s to early 1970s, a wide range of serious adverse effects were reported in association with these products. By that time, Defendants knew of serious diseases caused by unidentified agents transmissible by blood and Factor VIII and IX. Defendants failed to warn Plaintiff or the medical community of these adverse effects, violating industry standards and federal regulations.

PARAGRAPH NO. 21 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

22. By 1976, only a few years after Defendants' factor concentrate products went on the market, the United States Food and Drug Administration ("FDA") Bureau of Biologics held a conference titled *Unsolved Therapeutic Problems in Hemophilia*. The research articles compiled from the conference discussed the high incidence of disorders in patients using Defendants' products, such as liver dysfunction, enlarged spleen, Hepatitis B, and Non-A, Non-B Hepatitis ("NANB Hepatitis," later renamed Hepatitis C). The articles concluded that these disorders were tied to the patients' use of factor concentrates, and emphasized the risks entailed in producing such concentrates using plasma from paid donors. For instance, Robert Gerety of the FDA Bureau of Biologics, Division of Blood and Blood Products, reported that the agent or agents of NANB Hepatitis "appear to be blood borne, perhaps to be associated with a form of chronic hepatitis, and to represent a considerable risk to recipients who repeatedly require the administration of blood products." Gerety, et al., *Viral Antigens and Antibodies in People with Hemophilia* (1977). Gerety noted that "[t]he use of large plasma pools from paid donors no doubt contributes to the risk of HBV [Hepatitis B] infection from these products," and stated that "an all voluntary blood donor system is being pursued as a result of the known increased risk of PTH [post-transfusion hepatitis] from blood derived from commercial donors." As described below, however, Defendants not only refused to implement such a voluntary donor system, but instead recruited paid donors precisely because their hepatitis exposure resulted in plasma from which Defendants could make other commercially valuable products as well.

PARAGRAPH NO. 22 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. This paragraph purports to reference and quote research articles published in the 1970s. Baxter denies such references to the extent they are inconsistent with the plain meaning of the writings themselves and denies Plaintiff's characterization of the writings. By way of further answer, Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge. The remaining factual allegations directed to Baxter, if any, are denied.

23. At all times material to this Complaint, Defendants failed to adequately warn Plaintiff or his physicians of the serious adverse side effects of their products. Although Defendants' package inserts mentioned a risk that plasma "may" contain the causative agent of viral hepatitis, this warning was seriously deficient in that: (a) Defendants failed to disclose that the risk of hepatitis was essentially a 100% guarantee due to their practices of using high-risk donors and specifically recruiting for donors who had previously been exposed to Hepatitis B; (b) while "hepatitis" simply means inflammation of the liver, and may be a relatively benign, temporary condition, Defendants failed to warn that some forms of hepatitis transmitted by their products were believed to present a considerable risk of severe liver damage and a significantly elevated risk of liver cancer; (c) Defendants misleadingly stated that the source plasma used in preparation of their products had been found to be non-reactive for Hepatitis B surface antigen (HBsAg)—implying that no viral hepatitis was present in the plasma—and falsely stated that available methods were not sensitive enough to detect all units of potentially infectious plasma, failing to disclose that in fact Defendants had refused to implement the more sophisticated Hepatitis B Core antibody (HBc) test which would have excluded the majority of plasma contaminated by hepatitis; and (d) Defendants' labeling disclosed that their products were made from large pools of fresh human plasma, but failed to disclose that paid donors increased the risk of disease, and that the particular groups of paid donors targeted by Defendants were known to be the highest risk groups.

PARAGRAPH NO. 23 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. By way of further answer, Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical

and scientific knowledge. The remaining factual allegations directed to Baxter, if any, are denied.

24. The demand for and supply of anti-hemophilic factor rapidly increased during the 1970's, with commercially-manufactured concentrate accounting for a large proportion of the increase in supply. In 1977, a federal report projected that the volume of factor concentrates manufactured would increase substantially by 1980. Division of Blood Diseases and Resources, National Heart, Lung and Blood Institute, *Study to Evaluate the Supply-Demand Relationships for AHF and PTC Through 1980*, at page 8; hereinafter "NHLBI Report."

PARAGRAPH NO. 24 ANSWER: This paragraph does not allege any facts directed to Baxter but rather purports to reference a specific report. Baxter denies the allegations of this paragraph to the extent they are inconsistent with the plain meaning of the referenced report.

25. In order to sell more factor concentrates to this growing market, Defendants turned to the fastest and cheapest way of obtaining sufficient plasma, paid donors. Defendants recruited paid donors from those populations most likely to respond to the financial incentive to donate: poor inner city residents, drug abusers, prisoners, and residents of impoverished developing countries such as Haiti and Nicaragua.

PARAGRAPH NO. 25 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

26. Defendants purposefully sought out paid donors despite knowing that the risk of diseases transmissible by blood was far greater among paid donors than among volunteers. Because no test was yet available in the 1970s for the NANB Hepatitis virus, an essential means to prevent the virus from contaminating the plasma supply was to exclude donors with behaviors that were inconsistent with good health—precisely those populations from which Defendants were recruiting paid donors. Some studies indicated that paid donors were up to ten times more infectious than volunteer donors. For this reason, the National Blood Policy, adopted by the federal government in July 1973, advocated conversion to an all-volunteer blood supply. Defendants, however, not only continued to use paid donors, but also focused their recruiting efforts on the highest risk populations.

PARAGRAPH NO. 26 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is

required. This paragraph purports to reference various studies and reports. Baxter denies such references to the extent they are inconsistent with the plain meaning of the documents. The remaining factual allegations directed to Baxter, if any, are denied.

27. Defendants had an additional financial incentive for recruiting paid donors. Factor VIII and Factor IX are only two of many products that can be made for commercial sale from human plasma. According to the NHLBI Report, by the late 1970s at least 17 different therapeutic components of blood were manufactured by the process of "fractionating" plasma into its various elements. The NHLBI Report noted that, "as the costs of fractionation have increased, fractionators have produced as many products as possible from a liter of plasma." *Id.* at 65.

PARAGRAPH NO. 27 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. This paragraph purports to reference and quote a specific report. Baxter denies such references to the extent they are inconsistent with the plain meaning of the report. Baxter admits that plasma is a scarce resource and that Baxter made an effort not to waste this valuable resource that can be processed into various therapeutic applications. The remaining factual allegations directed to Baxter, if any, are denied.

28. Blood derivatives used as vaccines or therapeutics had particularly high economic value for Defendants. The NHLBI Report noted that plasma with a very high titer, or antibody level, for a corresponding antigen is "very expensive." *Id.* at 41. Such products are manufactured from source plasma drawn from donors who have been sensitized to a particular antigen. *Id.* The NHLBI Report specifically stated, however, that "plasma collected for high antibody titer **cannot** be used for fractionation into therapeutic products," such as Defendants' factor concentrate. *Id.* (emphasis added).

PARAGRAPH NO. 28 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. This paragraph purports to reference and quote a specific report the accuracy and

authenticity of which is not known to Baxter and Baxter therefore denies the allegations regarding such report. The remaining factual allegations directed to Baxter, if any, are denied.

29. Defendants targeted donors with high titers to Hepatitis B antigens in order to manufacture and sell Hepatitis B immunoglobulin (HBIG), a product that confers temporary immunity to the Hepatitis B virus. Despite the warning in the NHLBI report, Defendants used the same high-titer plasma obtained for making HBIG to manufacture their Factor VIII and IX products used by people with hemophilia. Defendants thus sought to maximize profits by producing "as many products as possible from a liter of plasma," while ignoring industry standards that precluded the use of high-titer plasma for other therapeutic products.

PARAGRAPH NO. 29 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. Baxter admits that high titer plasma is used to make hepatitis B immune globulin and that certain donors with the necessary high titers were sought for that purpose. The remaining factual allegations directed to Baxter, if any, are denied.

30. Beginning in about 1978, Defendants began targeting homosexual donors in known urban gay communities. Because urban homosexuals had been reported in the 1970s to have exceptionally high prevalence of Hepatitis B infection, Defendants knew that such donors would provide a reliable source of plasma for the manufacture of commercially valuable HBIG.

PARAGRAPH NO. 30 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

31. By the 1970's, it was also well-known in the public health community that urban homosexuals engaged in promiscuous sexual practices that rapidly transmitted other diseases, including NANB Hepatitis, which were transmitted by blood and were believed to have serious adverse consequences. Despite this knowledge, Defendants used the same plasma pool from urban homosexuals to manufacture both HBIG and Factor VIII and IX.

PARAGRAPH NO. 31 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

32. By the 1970s, it was also well-established that plasma from prison populations carried a high risk of hepatitis and other blood-borne diseases, primarily because of the concentration of intravenous (IV) drug users in prisons. By 1974, the alanine aminotransferase ("ALT") test was available to test for elevated levels of liver enzymes called SGOT that indicate the presence of hepatitis. Prisoners were associated with SGOT levels of over 60 IUs per ml, a level that increases the risk of Hepatitis C transmission by a factor of 6. Despite knowledge of this risk, Defendants actively recruited prisoners for plasma used to manufacture Factor VIII and IX, while concealing or failing to disclose the risk to Plaintiff, his physicians, or the FDA.

PARAGRAPH NO. 32 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. By way of further response, this paragraph purports to cite statistics about unidentified "prisoners," ostensibly based on some unidentified report, the accuracy and authenticity of which is not known to Baxter and Baxter therefore denies the allegations regarding these statistics and report. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

33. In light of Defendants' special knowledge of the disease patterns among urban homosexuals and prisoners, and their recruitment of such donors for Factor VIII and IX manufacture, Defendants had duties to: (a) discontinue the practice of using such high risk donors; (b) disclose the risk to Plaintiff, his physicians, and the FDA, including the ongoing risk of continuing to use Factor VIII and IX previously manufactured with high risk plasma and still marketed to patients; (c) implement procedures to kill blood-borne diseases in the products; and (d) recall existing products from distribution or further use. Instead, Defendants continued to conceal their recruitment of high-risk donors and to resist warnings and recalls, and failed to implement procedures to make their products safe.

PARAGRAPH NO. 33 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter specifically denies "concealing" anything.

34. By no later than 1978, Defendants knew of the availability of a new test to determine whether an individual had a history of viral hepatitis, which would have disqualified the donor from providing plasma for the manufacture of Factor VIII or IX. By testing a person's serum for the presence of the core to the Hepatitis B antibody, a history of viral hepatitis could be verified. This was known as the "HBc test." Published, peer-reviewed literature shows that the HBc test was in use by researchers to determine that homosexual AIDS victims had a history of viral hepatitis by no later than December 1981. Gottlieb, et al., *Pneumocystis Carinii Pneumonia and Mucosal Candidiasis in Previously Healthy Homosexual Men*, 305 New Eng. J. Med. 1425-1431 (1981).

PARAGRAPH NO. 34 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

35. Use of the HBc test would have eliminated approximately 75% of homosexual plasma donors and over 90% of promiscuous urban homosexuals. It would have eliminated almost 100% of intravenous drug users.

PARAGRAPH NO. 35 ANSWER: The allegations of this paragraph are denied.

36. Use of the HBc and ALT tests together by Defendants by 1981 would have eliminated the vast majority of the transmitters of HCV from the blood and plasma pools of the nation, before the height of the Hepatitis C epidemic. If Defendants had implemented this test in a timely manner, Plaintiff more likely than not would not have been infected with HCV as a result of factor concentrate use.

PARAGRAPH NO. 36 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

37. As noted below, federal regulations required plasma donors to be in good health, and donors with a "history of viral hepatitis" were by definition unacceptable as blood or blood plasma donors. Persons with a history of viral hepatitis were excluded not only because of the risk of transmitting Hepatitis B, but because such a history indicated a lifestyle or previous behavior of the prospective donor that carried the risk of transmitting other viruses in addition to hepatitis. A reasonable and prudent plasma fractionator would not accept a HBc positive donor and expect to be in compliance with federal regulations as of 1978.

PARAGRAPH NO. 37 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. By way of further response, this paragraph purports to reference and interpret federal regulations. Baxter denies every allegation inconsistent with the plain language of the regulations as applied and interpreted by the FDA during the relevant period. The remaining factual allegations directed to Baxter, if any, are denied.

38. After public reports of the first hemophilia AIDS cases in July 1982, government officials urged Defendants to implement the HBc test as a "surrogate" or "marker" to eliminate plasma contaminated by the transmitter of AIDS and Hepatitis C. HBc testing was also strongly suggested to Defendants by the CDC at a meeting of the United States Public Health Service ("PHS") on January 4, 1983. Despite this urging, Defendants continued to use contaminated plasma donations that would have been excluded by the HBc test and continued to conceal from Plaintiff, his physicians, and the FDA the dangerous practice of targeting donors at highest risk for hepatitis. At a January 6, 1983 meeting of Defendants' trade association, the Pharmaceutical Manufacturer's Association, Defendants agreed not to implement the highly effective HBc donor screening, and instead opted to use ineffective donor questionnaires that did little to screen out donors at high-risk for Hepatitis C transmission.

PARAGRAPH NO. 38 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter specifically denies that HBc testing was "highly effective" for screening donors.

39. As late as December 13, 1983, years after the HBc test was available, a memorandum from CUTTER's responsible head, Stephen Ojala, reporting back on a meeting held by Defendants, shows that Defendants conspired to propose a "task force" to further study the use of HBc as an intentional, bad faith "delaying tactic for the implementation" of the test.

PARAGRAPH NO. 39 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of

further answer, Baxter specifically denies that it ever conspired with anyone to do anything. Baxter further explicitly denies that it participated in any "delaying tactic" and further denies that it participated in the preparation of any other defendant's internal documents or adopted the representations in such documents as its own.

C. Answer to Plaintiff's Allegations Regarding Heat Treatment and Solvent Detergent

40. In the late 1970s and early 1980s, it was recognized that viruses were in all factor concentrate products. Treatment with solvents and/or detergents was available at that time to eliminate many of these viruses, including HCV. Defendants were required to take reasonable steps to eliminate contamination, but Defendants failed to utilize these available technologies to eliminate the viruses in a timely manner.

PARAGRAPH NO. 40 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter admits that in the late 1970's and early 1980's hepatitis was recognized as the sole known viral pathogen transmissible via Factor VIII and Factor IX. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

41. Solvent and/or detergent treatment was available to Defendants by the late 1970's as a simple and effective method of eliminating viruses in factor concentrate products. Solvents and/or detergents effectively kill viruses such as HCV by destroying the viruses' lipid envelope. This method is simpler than heat treatment, and unlike heat treatment does not interfere with the Factor VIII and IX proteins needed for blood clotting.

PARAGRAPH NO. 41 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

42. Solvents and/or detergents were well-known, commercially available products as of the 1970's, and studies in which solvent and/or detergent treatment was used to disrupt viruses were published in the 1970's in peer-reviewed journals. In 1980, Dr. Edward Shanbrom, a former Baxter scientist, received a patent for a detergent treatment process for viral inactivation of factor concentrate. Dr. Shanbrom describes the implementation of this process as "as easy as washing your hands."

PARAGRAPH NO. 42 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. Baxter specifically denies that solvent detergents were well known or commercially available for use in factor concentrates in the 1970's or that peer review articles addressed solvent detergents in factor concentrates at that time. The remaining factual allegations directed to Baxter, if any, are denied.

43. After receiving the patent, Dr. Shanbrom approached Defendants about implementing his method, but Defendants refused to heed Dr. Shanbrom's advice. Defendants refused to even commit any resources to investigate the solvent and/or detergent method.

PARAGRAPH NO. 43 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

44. Defendants were notified of the successful use of organic solvents to destroy lipid viruses, including NANB, in factor concentrates by the New York Blood Center ("NYBC") at the National Hemophilia Federation's meeting on October 27, 1983.

PARAGRAPH NO. 44 ANSWER: Baxter admits only that it was present at a meeting in October 1983 at which Bernard Horowitz of the New York Blood Center reported on his ground breaking research involving the attempted viral inactivation of lipid coated viruses.

Baxter specifically denies the implication that the information presented at such meeting was anything more than novel research. To the extent the remaining factual allegations of this paragraph are directed to Baxter, they are denied.

45. In 1984, Dr. Prince and Dr. Horowitz of the NYBC published the results of their successful use of the solvent detergent process in well-known medical journals. They offered to license the process to Defendants for a reasonable fee. In 1985, the NYBC obtained a license from the FDA to market a solvent detergent inactivated factor concentrate.

PARAGRAPH NO. 45 ANSWER: Baxter admits that in 1984, Drs. Prince and Horowitz published an article about a solvent and a detergent. Baxter further admits that in or around 1985, the NYBC obtained a license for a solvent detergent treated factor concentrate. To the extent the remaining factual allegations are directed to Baxter, they are denied.

46. By March, 1984, Defendants obtained licenses to sell Factor VIII treated with dry heat to inactivate viruses, and Defendants had obtained such licenses for Factor IX by October, 1984. The FDA did not allow them to label these products as hepatitis safe. By fall of 1984, Defendants were notified by treaters that previously-untreated patients in their clinical trials using their dry heated products developed elevated ALT enzymes, indicative of NANB infections.

PARAGRAPH NO. 46 ANSWER: To the extent the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. Baxter admits that its heat-treated Factor VIII concentrate was licensed in 1983 and that it obtained a license for heat-treated Factor IX in 1984 as part of Baxter's ongoing effort to eliminate hepatitis. All remaining factual allegations directed to Baxter, if any, are denied.

47. Defendants were therefore aware in 1984 that dry heat did not effectively inactivate the virus that causes HCV, and that solvent detergent treatment methods did eliminate the risk of HCV infection, but chose not to employ the effective and efficient solvent detergent technology. Instead, Defendants continued to sell their contaminated dry heat product for at least four more years, resulting in the needless infection of Plaintiff and many other hemophiliacs.

PARAGRAPH NO. 47 ANSWER: To the extent the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

48. A recent CDC study documented the comparative effectiveness of the dry heat and solvent detergent inactivation methods. The study reported that "84% of previously untreated patients infused with dry-heated Factor VIII products developed non-A, non B hepatitis . . . ." Soucie, Richardson, Evatt et al., *Risk Factor for Infection with HBV and HCV in a Large Cohort of Hemophiliac Males*, 41 Transfusion 338-343 (2001).

PARAGRAPH NO. 48 ANSWER: This paragraph does not include allegations directed to Baxter but rather purports to recite medical and scientific information. Baxter denies such statements to the extent they are inconsistent with the state of medical and scientific knowledge. This paragraph further purports to quote a published article, the accuracy and authenticity of which are not known to Baxter, and Baxter therefore denies such quotation and further denies Plaintiff's characterization of the quotation.

49. The same CDC study reported that "solvent detergent treatment of blood components [was] found to be more effective against enveloped viruses than heat treatment ... No cases of HBV, HCV, or HIV transmission through solvent detergent virus inactivated products have been found in prospective studies of previously untreated patients..."

50. The study further reported "in our data, the first dramatic decline in HCV prevalence appears in the 1987 birth cohort. The drop in HCV transmission correlates with the licensing of solvent detergent treatment of Factor IX products in 1987. In addition, this cohort would have been the first to benefit from the screening of blood donors using the surrogate markers ALT (begun in late 1986) and anti-HBc (begun in 1987), testing that was associated with a markedly decreased risk of HCV infection from blood transfusions."

PARAGRAPH NOS. 49-50 ANSWER: These paragraphs do not include allegations directed to Baxter but rather purport to recite medical and scientific information. Baxter denies such statements to the extent they are inconsistent with the state of medical and scientific

knowledge. These paragraphs further purport to quote a published article, the basis, accuracy and authenticity of which are not known to Baxter, and Baxter therefore denies such quotations.

51. The study states further that "the residual transmissions after 1987 possibly represent the use of product already manufactured or product manufactured during the interval required to implement the new technology. The 18-month shelf life of factor concentrates placed those people with hemophilia born as late as 1989 at risk of infection." The study goes on to recommend testing for all people with hemophilia who received infusions of Defendants' blood products prior to 1992.

PARAGRAPH NO. 51 ANSWER: This paragraph does not include allegations directed to Baxter but rather purports to recite medical and scientific information. Baxter denies such statements to the extent they are inconsistent with the state of medical and scientific knowledge. This paragraph further purports to quote a published article, the basis, accuracy and authenticity of which are not known to Baxter, and Baxter therefore denies such quotation and further denies Plaintiff's characterization of the quotation.

52. By 1988, it was clear to the medical and scientific community what Defendants had long known: dry-heated factor concentrates were transmitting the potentially deadly NANB virus, and safer products were available. This knowledge prompted the CDC to publish recommendations that dry-heated products no longer be used by hemophiliacs. Defendants continued sales of their dry-heated products after these warnings however, and never undertook a large-scale recall of dry-heated product. Defendants finally introduced solvent detergent-treated products to the market in 1988 and 1989, but continued to sell their NANB contaminated dry-heated factor concentrates after this date.

PARAGRAPH NO. 52 ANSWER: To the extent the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. Baxter admits that for years, the potential transmission of viral hepatitis was a well-known risk of all blood and plasma based therapies. Baxter further admits that it introduced a solvent detergent treated therapy in 1988. By way of further answer, Baxter states that to the extent this paragraph references "what was clear to the medical community" or "what prompted

the CDC" to allegedly take certain actions, Baxter is without knowledge or information sufficient to form a belief as to the state of mind or motivation of such groups and therefore denies all such allegations. This paragraph further references alleged but unidentified CDC "recommendations," the existence, accuracy, and authenticity of which are unknown to Baxter and Baxter therefore denies them. Baxter further states that it is unaware of any large-scale recall of heat-treated factor concentrate. The remaining factual allegations directed to Baxter, if any, are denied.

53. The failure of Defendants to implement solvent and/or detergent viral inactivation techniques in a timely manner, to warn of the risk that dry heat treated Factor VIII and IX blood products could transmit HCV, and to recall dry heat treated products that posed this risk caused the needless infection of thousands of people with hemophilia with HCV, including Plaintiff. Even after Defendants knew or should have known that solvent and/or detergents effectively destroyed HCV, they continued to sell dry heat treated Factor VIII and IX, and refused to recall these dangerous products from the market.

PARAGRAPH NO. 53 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

D. Answer to Allegations of Misrepresentation and Fraudulent Concealment

54. Defendants engaged in a pattern and practice of fraudulent concealment of their dangerous practices, fraudulent misrepresentations regarding their efforts to assure safety, and fraudulent misrepresentations regarding the risk of Hepatitis C, in order to maintain profits from both factor concentrates and HBIG. A summary of Defendants' fraudulent misrepresentations and concealment is set forth below.

PARAGRAPH NO. 54 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied. Baxter specifically denies misrepresenting or fraudulently concealing anything.

55. On July 27, 1982, a meeting of the Public Health Service was held as the result of the CDC's report that three people with hemophilia had contracted AIDS. The responsible heads

of Defendants were in attendance, along with officials from the National Hemophilia Foundation, CDC and FDA. Defendants were aware that they had used plasma from known, targeted homosexuals in the manufacture of their Factor VIII and IX blood products. These products had a shelf life of two years, and were either in production or already on the shelves in pharmacies waiting to be infused by people with hemophilia who purchased them. Defendants failed to disclose these facts at the meeting where CDC officials were present, despite knowledge that the CDC's primary concern at that meeting was the contamination of Factor VIII and IX by the agent that transmitted AIDS, which, like hepatitis, was already well-known to be epidemic in the targeted homosexual population. (CUTTER memorandum dated August 3, 1982.)

PARAGRAPH NO. 55 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

56. In or about December, 1982, Rodell, the responsible head for BAXTER, entered into an agreement with officials of the FDA to the effect that BAXTER would no longer use prison plasma in the production of factor concentrates. In fact, BAXTER, unbeknownst to the FDA, continued to use prison plasma in factor concentrate production through October 1983. BAXTER memorandum dated October 20, 1983.

PARAGRAPH NO. 56 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

57. On January 5, 1983, an AIDS meeting was held at Children's Orthopedic Hospital in Los Angeles, California, the largest hemophilia treatment center in the United States. Representatives of Defendants were present at the meeting with treaters and patients. A patient asked representatives from Defendants the following question: "Is the plasma from homosexuals, prisoners, Haitians or other high risk persons being used in the manufacture of concentrates?" Defendants did not admit targeting or using plasma from homosexuals, prisoners or inner city IV drug abusers. Defendants' representatives made no response to the question, thereby concealing the true risk created by the use of plasma from known homosexuals, IV drug abusers and prisoners in the manufacture of factor concentrates.

PARAGRAPH NO. 57 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. Further, this paragraph purports to quote a question followed by statements

characterizing Baxter's response or non-response thereto. In addition to being incomprehensible, the documentary source of this quotation is unidentified. Baxter is without knowledge or information sufficient to form a belief as to the existence, accuracy or authenticity of such document and therefore denies the alleged quotation and all allegations related thereto. Baxter further states that it did not "target" or use high-risk plasma. The remaining factual allegations directed to Baxter, if any, are denied.

58. At the January 5, 1983 meeting, and in the presence of the patients, one of the treating physicians, Dr. Kasper, asked CUTTER'S Stephen Ojala: "These [plasma] centers seem to be in rundown centers of town. Is there a move to move them to rural towns?" Ojala answered: "Many of the centers are in smaller communities and in towns such as Ypsilanti, Seattle, Clayton, NC., and San Diego. We do not have centers in L.A. or San Francisco." This answer was misleading because Ojala failed to state that CUTTER'S largest and first plasma center was located at Arizona State Penitentiary. CUTTER also had a center at the Las Vegas Prison. Ojala and CUTTER were well aware of the CDC's and FDA's concern over use of prison plasma, due to homosexual practices and drug abuse in the prison donor population. Many of CUTTER's centers were in inner city areas frequented by IV drug abusers, such as downtown Oakland, California. CUTTER had also used plasma from centers which targeted known homosexuals. In August 1982, CUTTER quarantined plasma from the Valley Medical Center, a center which targeted known homosexuals, because a donor was hospitalized with full blown AIDS. The plasma was intended for factor concentrate and HBIG production, but was not used because it had thawed on the way to the processing plant. Upon receiving a report of this incident from CUTTER, the FDA indicated a recall might have been necessary if the plasma had been incorporated into factor concentrate final product. Ojala omitted any mention of these facts and circumstances in his response to Dr. Kasper regarding the location of their plasma centers. (CUTTER memorandum dated January 5,1983.)

PARAGRAPH NO. 58 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required.

59. On January 14, 1983, responsible heads from Defendants attended a meeting of the National Hemophilia Foundation ("NHF"). Defendants were very concerned that the NHF would insist on a recommendation that HBc testing be implemented, consistent with the CDC recommendation 10 days earlier. In order to defer a NHF recommendation that HBc testing be used, Michael Rodell, a representative of Baxter, told NHF officials on behalf of Defendants, that surrogate testing was in the "R and D," or "Research and Development," stage currently.

Rodell concealed the fact that the CDC had strongly recommended use of the HBc antibody test as a screening device for high risk donors. The HBc antibody test was not in the "R and D" stage, and was suitable for use as a screening device for high risk AIDS and Hepatitis C donors. In fact, the HBc test had been approved in 1979 by the FDA as a test to be used to ascertain a history of previous hepatitis B infection, and to screen blood and plasma donors. Donors with a hepatitis history were specifically prohibited pursuant to the federal regulations (21 C.F.R. § 640.63). Rodell acknowledged that implementation of the HBc test would eliminate high titered immunoglobulin donors, but failed to disclose that opposition to use of the test was based on economic rather than safety concerns.

PARAGRAPH NO. 59 ANSWER: To the extent the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter admits that on January 14, 1983 representatives from various government agencies such as the FDA and CDC, representatives of various voluntary blood agencies, and representatives from the fractionation industry attended a meeting of the National Hemophilia Foundation. Baxter further admits only that it seriously considered the possibility of using HBc testing and that Baxter did perform an informal survey regarding HBc testing. The remaining factual allegations directed to Baxter are denied. By way of further answer, Baxter specifically denies that the CDC ever recommended HBc testing and specifically denies that HBc testing was ever licensed for any use other than diagnostic purposes. In fact, after 1983 the FDA explicitly confirmed that HBc testing was not to be used for plasma screening.

60. At the January 14, 1983 meeting, Defendants concealed their advertising in publications distributed among urban homosexuals, for the specific purpose of attracting them to plasma centers which supplied high titered plasma to Defendants. Defendants also concealed their extensive use of prison plasma and failed to reveal their "gentlemen's agreement" with the FDA to discontinue use of these plasma sources immediately. (CUTTER Memorandum dated January 17, 1983.)

PARAGRAPH NO. 60 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is

required. To the extent that these allegations are factual and directed to Baxter, Baxter admits that it openly discussed its plans to phase out prison plasma during the coming year. Baxter specifically denies the allegation that it affirmatively concealed anything. The remaining factual allegations directed to Baxter, if any, are denied.

61. On or about December 15, 1983, Rodell, then the head of Armour Pharmaceutical Company, Inc., told members of the federal Blood Product Advisory Committee (BPAC) and FDA officials that Defendants wanted a three-month deferral in implementation of any recommendations by the BPAC or FDA that HBc testing be required for plasma donors. Rodell told the FDA that the purpose of the deferral was to prepare a response to the proposed recommendation. In fact, Defendants had agreed to seek the three-month hiatus as a "delaying tactic" to avoid implementing the test, and the request for a deferral was made in bad faith. (CUTTER memorandum dated December 13, 1983.)

PARAGRAPH NO. 61 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and thus no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter admits that at a meeting on or about December 15, 1983, Michael Rodell, an employee of Armour, proposed to BPAC and certain members of the FDA, the creation of a Task Force to evaluate the utility of HBc testing and provide additional information in three months. Baxter specifically denies that this was a delaying tactic and further denies that the request for the establishment of a Task Force was made in bad faith. The remaining factual allegations directed to Baxter, if any, are denied.

62. Defendants fraudulently misrepresented the risk of Hepatitis C due to factor concentrates, failed to disclose accurate warnings of the risk to Plaintiff or his physicians, and fraudulently purported to be doing "everything possible" to improve safety, when in fact Defendants maximized the risk by recruiting high-risk donors and by resisting and obstructing HBc testing, treatment with solvents and/or detergents, and other measures that would truly have reduced the risk.

PARAGRAPH NO. 62 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. Baxter specifically denies that it engaged in any fraudulent activities, failed to disclose accurate warnings or recruited high risk donors. All remaining factual allegations directed to Baxter, if any, are denied.

E. Answer to Allegations Regarding Federal Regulations

63. Blood derivatives such as Factor VIII and IX are prescription biologicals subject to federal regulation as both "biological products" and "drugs." Public Health Service Act, "Regulation of Biological Products," 42 U.S.C. § 262; Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.* (2005).

(a) 21 U.S.C. § 331(b) prohibited and continues to prohibit "adulteration or misbranding of any ... drug . . . ."

(b) 21 U.S.C. § 351(a)(2)(B) provided and continues to provide that "[a] drug . . . shall be deemed to be adulterated . . . if ... the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety. . . ."

(c) 21 U.S.C. § 352 provided and continues to provide that "[a] drug... shall be deemed to be misbranded. .. if its labeling is false or misleading in any particular."

(d) 21 U.S.C. § 352(f)(2) provided and continues to provide that a drug shall be deemed to be "misbranded" unless its labeling bears "adequate warnings against use. . . where its use may be dangerous to health."

(e) 21 U.S.C. § 352(n) provided and continues to provide that a drug shall be deemed to be "misbranded" unless the labeling included information concerning side effects and contraindications as required in federal regulations.

(f) 21 U.S.C. § 321(n) provided and continues to provide that if an article is alleged to be misbranded because the labeling or advertising is misleading, then the determination of whether the labeling or advertising is misleading shall take into account "not only representations made or suggested" by affirmative statements, "but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use" of the drug.

PARAGRAPH NO. 63 ANSWER: The allegations of this paragraph, including all of its subparts, constitute legal conclusions and therefore no response is required. Further, this paragraph, including its subparts, purports to quote provisions of the United States Code. Baxter denies any quotations, or portions thereof, which are not in conformity with the exact language of the referenced statute and, in any event, denies Plaintiff's characterization of such language.

64. At all times material to this Complaint, 21 C.F.R. § 201.57(e) provided and continues to provide as follows, with respect to information to be provided with the sale of Defendants' products:

> Warnings: Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association with a drug; a causal relationship need not have been proved.

65. At all times material to this Complaint, 21 C.F.R. § 200.5 provided and continues to provide as follows:

> Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians and others responsible for patient care. In the public interest, such mail shall be distinctive in appearance so that it will be promptly recognized and read.

66. At all times material to this Complaint, Part 606 of 21 C.F.R. set forth and continues to set forth "Current Good Manufacturing Practices" for biological products generally, and 21 C.F.R. § 640, *et seq.*, set forth additional good manufacturing practices for blood and plasma biologicals.

67. At all times material to this Complaint, 21 C.F.R. § 606.140(a) provided and continues to provide:

> Laboratory control procedures shall include: The establishment of scientifically sound and appropriate specifications, standards and test procedures to assure that blood and blood components are safe, pure, potent and effective.

68. At all times material to this Complaint, 21 C.F.R. § 640.60 defined and continues to define "Source Plasma" as:

> the fluid portion of human blood collected by plasmapheresis, and is intended as source material for further manufacturing use.

69. At all times material to this Complaint, 21 C.F.R. § 640.63(c), (1999), titled "Qualification of Donor," provided and continues to provide as follows with respect to donors of source plasma:

> Donors shall be in good health on the day of donation, as indicated in part by: . . . (9) freedom from any disease, other than malaria, transmissible by blood transfusion, in so far as can be determined by history and examination indicated in this section; (10) freedom of the arms and forearms from skin punctures or scars indicative of addiction to self-injected narcotics; (11) freedom from a history of viral hepatitis; (12) freedom from a history of close contact within six months of donation with an individual having viral hepatitis; . . . .

Further, 21 C.F.R. § 640.63(a) provided and continues to provide that the method of determining "suitability of a donor" included "tests" as well as the taking of a history and physical examination.

PARAGRAPH NOS. 64-69 ANSWER: The allegations of these paragraphs constitute legal conclusions and therefore no response is required. Further, these paragraphs purport to quote provisions of the Code of Federal Regulations. Baxter denies any quotations, or portions thereof, which are out of conformity with the exact language of the referenced regulation. Moreover, Baxter is without knowledge or information sufficient to form a belief as to what times Plaintiff believes are "material to this Complaint" and therefore denies the allegations of these paragraphs on that basis and, in any event, Baxter denies Plaintiff's characterization of such language.

70. The foregoing statutes and regulations are evidence of the standard of care Defendants should have employed in the manufacture and sale of Factor VIII and Factor IX. Defendants violated the foregoing regulations and/or failed to comply with applicable standards of care by: (a) marketing "adulterated" products that were unsafe as a result of failure to comply with "Current Good Manufacturing Practice"; (b) marketing "misbranded" products that were misleading and failed to disclose or warn of health dangers; (c) failing to warn of serious adverse reactions and potential safety hazards as soon as there was reasonable evidence of an association with their products; (d) failing to exclude intravenous drug users who were unsuitable donors; (e) failing to exclude donors with a history of viral hepatitis who were unsuitable donors; (f) affirmatively seeking out unsuitable donors known to have viral hepatitis antibodies, as well as prison populations known to include substantial numbers of intravenous drug users, for inclusion of their plasma in the pools used to make Factor VIII and Factor IX; (g) failing to disclose their use of dangerous donors; and (h) failing to use appropriate tests and/or procedures to assure their products were safe.

PARAGRAPH NO. 70 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter specifically states that it at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

F. Answer to Allegations Regarding Group Liability

71. All Defendants likely to have caused the harm to Plaintiff are parties to this lawsuit and properly before the court.

PARAGRAPH NO. 71 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

72. The conduct of Defendants, with respect to their Factor VIII and Factor IX products and related plasma collection methods, was tortious.

PARAGRAPH NO. 72 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

73. The harm which has been caused to Plaintiff resulted from the conduct of one, or various combinations of the Defendants, and, through no fault of Plaintiff, there may be uncertainty as to which one or combination of Defendants caused the harm.

PARAGRAPH NO. 73 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

74. The burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by the Plaintiff.

PARAGRAPH NO. 74 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

75. Factor concentrates were manufactured using the same fractionation method by all Defendants. As such, during the relevant years, factor concentrates were a fungible product, and physicians prescribed the products interchangeably without regards to brand names.

PARAGRAPH NO. 75 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. Baxter denies that its factor concentrate was "manufactured" or that it was "fungible." Baxter's factor concentrate was processed in accordance with Baxter's own proprietary procedures specifically approved and licensed by the Food and Drug Administration. Moreover, no two factor concentrate therapies were the same and although some hemophiliacs could successfully use more than one brand of factor concentrate, it was not uncommon for physicians to prescribe specific brands for specific hemophiliacs for whom certain therapies provided a better therapeutic outcome. The remaining factual allegations directed to Baxter, if any, are denied.

76. The factor concentrates manufactured by Defendants contained the same design flaws. They were all manufactured from paid donor plasma, which was at highest risk for Hepatitis B and Hepatitis C viral transmission. In addition, all Defendants' factor concentrates were made from large pools consisting of 5,000 to over 20,000 paid donors, which further magnified the risk of viral transmission.

PARAGRAPH NO. 76 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter admits

only that it processed its factor concentrates from the pooled plasma of multiple donors. The remaining factual allegations directed to Baxter, if any, are denied.

77. None of the factor concentrates made by Defendants during the relevant time period were subjected to viral inactivation processes such as solvent and/or detergent treatment that were effective against HCV. Therefore, all of Defendants' factor concentrates carried a significant risk of HCV transmission during this time. In addition, all of Defendants' factor concentrate products were similarly misbranded. All of the products failed to warn of the known risks enumerated in this complaint.

PARAGRAPH NO. 77 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further response Baxter states that to the extent there were any risks associated with the use of factor concentrate about which Baxter knew or should have known and which gave rise to a duty to warn, Baxter at all times discharged such duty through appropriate and adequate FDA approved warnings to physicians in accordance with applicable statutes and regulations and the existing state of medical and scientific knowledge.

V. ANSWER TO ALLEGATIONS REGARDING TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

78. Any and all potentially applicable statutes of limitations have been tolled by Defendants' affirmative and intentional acts of fraudulent conduct, concealment, and misrepresentation, alleged above, which estop Defendants from asserting statutes of limitation. Such acts include but are not limited to intentionally covering up and refusing to disclose use of high-risk plasma; selling products known to be contaminated; suppressing and subverting medical and scientific research; and failing to disclose and suppressing information concerning the risk of HCV transmission from Defendants' contaminated factor concentrates.

PARAGRAPH NO. 78 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of

further answer, Baxter specifically denies any acts of fraudulent conduct, concealment or misrepresentation.

79. Defendants are estopped from relying on any statutes of limitation because of their fraudulent concealment and misrepresentation alleged above. Defendants were under a duty to disclose the precise risks of HCV transmission from their contaminated factor concentrate because this is nonpublic information over which they had exclusive control, because Defendants knew this information was not readily available to people with hemophilia like Plaintiff, and because this information was relevant to such people in deciding whether to use Defendants' factor concentrate.

PARAGRAPH NO. 79 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. By way of further answer, the remaining factual allegations directed to Baxter, if any, are denied. Baxter specifically denies any acts of fraudulent conduct, concealment or misrepresentation. Baxter further denies that it owed a duty to act in any manner with regard to the processing of factor concentrates other than the manner in which it acted.

80. Until very recently, Plaintiff had no knowledge that Defendants were engaged in much of the wrongdoing alleged herein. Because of the fraudulent and active concealment of the wrongdoing by Defendants, including but not limited to deliberate efforts—which continue to this day—to give Plaintiff the materially false impression that Defendants undertook all feasible safety precautions to reduce the risk of HCV transmission from their contaminated factor concentrates, Plaintiff could not reasonably have discovered the wrongdoing any time prior to this time, nor could Plaintiff have, as a practical matter, taken legally effective action given the unavailability, until very recently, of internal memoranda and other documents (as generally described herein) as evidence in support of Plaintiff's claims. Defendants still refuse to admit and continue to conceal their wrongdoing, and therefore Defendants' acts of fraudulent concealment and misrepresentation continue through the present time.

PARAGRAPH NO. 80 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter specifically denies any acts of fraudulent conduct, concealment or

misrepresentation. Baxter further denies that Plaintiff suffered any injuries as a result of any wrongful acts or omissions by Baxter.

VI. ANSWER TO ALLEGATIONS REGARDING CLAIMS FOR RELIEF

Answer to Plaintiff's Fraudulent Omission and Concealment Allegations

81. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

PARAGRAPH NO. 81 ANSWER: Baxter incorporates by reference its responses to all preceding paragraphs as if fully set forth herein and further answers as follows:

82. Defendants had a confidential and special relationship with Plaintiff due to: (a) Defendants' vastly superior knowledge of the health and safety risks relating to Factor VIII and Factor IX; (b) Defendants' sole and/or superior knowledge of their dangerous and irresponsible plasma collection practices; and (c) Defendants' direct communications with the hemophiliac community through newsletters that purported to accurately convey the risk of NANB. As a result, Defendants had an affirmative duty to fully and adequately warn the hemophiliac community, including Plaintiff, his guardians, and his physicians, of the true health and safety risks related to their Factor VIII and Factor IX blood products and constituent plasma and a duty to disclose their dangerous and irresponsible plasma collection practices. Independent of any special relationship of confidence or trust, Defendants had a duty not to conceal the dangers of their products to Plaintiff, his guardians, and his physicians.

PARAGRAPH NO. 82 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter denies that it owed any duty to act in any manner with regard to the processing and distribution of factor concentrates other than the manner in which it acted. Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

83. Misrepresentations made by Defendants about the health and safety of their factor concentrate products independently imposed a duty upon Defendants to fully and accurately

disclose to the hemophiliac community, including Plaintiff, his guardians, and his physicians, the true health and safety risks related to Factor VIII and Factor IX and its constituent plasma, and a duty to disclose their dangerous and irresponsible plasma collection practices.

PARAGRAPH NO. 83 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter denies that it owed any duty to act in any manner with regard to the processing and distribution of factor concentrates other than the manner in which it acted. Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

84. In connection with their Factor VIII and Factor IX products, Defendants fraudulently and intentionally concealed important and material health and safety product risk information from Plaintiff, his guardians, the hemophiliac community, and treating physicians, all as alleged in this Complaint.

PARAGRAPH NO. 84 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter specifically denies that it fraudulently or intentionally concealed any information from Plaintiff. Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

85. Any of the following is sufficient to independently establish Defendants' liability for fraudulent omission and/or concealment:

(a) Defendants fraudulently concealed the health and safety hazards, symptoms, diseases and/or health problems associated with their Factor VIII and Factor IX blood products and related plasma collection activities;

(b) Defendants fraudulently concealed the practice of using unsuitable plasma from unsuitable donors in the manufacture of their Factor VIII and Factor IX blood products;

(c) Defendants fraudulently concealed their practice of avoiding the use of available technology to detect viruses in their Factor VIII and Factor IX blood products and the components thereof;

(d) Defendants fraudulently concealed their practice of avoiding the use of available technology to destroy viruses in their Factor VIII and Factor IX blood products and the components thereof; and/or

(e) Defendants fraudulently concealed information about the known comparative risks and benefits of the use of their Factor VIII and Factor IX and the relative benefits and availability of alternate products and therapies.

PARAGRAPH NO. 85 ANSWER: The allegations of these paragraphs constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. By way of further answer, Baxter specifically denies that it fraudulently or intentionally concealed any information from Plaintiff. Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

86. Defendants knew that Plaintiff, his guardians, the hemophiliac community, and physicians would regard the matters Defendants concealed to be important in determining a course of treatment, including the decision whether to use their Factor VIII and/or Factor IX blood products.

PARAGRAPH NO. 86 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter specifically denies that it concealed any information from anyone.

87. As a direct and proximate result of Defendants' fraudulent concealment and suppression of material health and safety risks relating to their Factor VIII and Factor IX blood products and of Defendants' dangerous and irresponsible plasma collection practices, Plaintiff has suffered and will continue to suffer injury, harm and economic loss. As the direct, proximate

and legal result of the Defendants' fraudulent concealment and suppression of material health and safety risks relating to their Factor VIII and Factor IX blood products and of Defendants' dangerous and irresponsible plasma collection practices, Plaintiff has been injured and has incurred damages, including but not limited to physical injuries to his person, medical expenses in the past, past disability, past loss of use of the body, and past physical and mental pain and suffering; and may incur in the future medical and hospital expenses, permanent disability, loss of use of the body, physical and mental pain and suffering, and loss of the enjoyment of life.

PARAGRAPH NO. 87 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. By way of further answer, Baxter specifically denies that it fraudulently or intentionally concealed any information from Plaintiff. Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

88. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

PARAGRAPH NO. 88 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required.

89. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

PARAGRAPH NO. 89 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. Baxter specifically denies that its conduct was malicious, intentional, outrageous, willful or wanton or that Plaintiff was injured or suffered damages as a result of a wrongful act or omission by Baxter.

90. Plaintiff is informed and believes that Defendants utilize retention policies that provide for scheduled destruction of documents and other items, which may result in the knowing, negligent, or inadvertent destruction of documents, data, and materials relevant and necessary to adjudication of this action, including, but not limited to, records identifying batch or lot numbers of Defendants' products shipped to particular treatment facilities, which may facilitate product tracing. This risk warrants an order from this Court that such evidence (including all documents, data compilations, and tangible things within the meaning of Rule 26 of the Federal Rules of Civil Procedure) be preserved and maintained for use in these proceedings.

PARAGRAPH NO. 90 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required from Baxter. The remaining factual allegations directed to Baxter, if any, are denied.

Answer to Plaintiff's Breach of Implied Warranty Allegations

91. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

PARAGRAPH NO. 91 ANSWER: Baxter incorporates by reference its responses to all preceding paragraphs as if fully set forth herein and further answers as follows:

92. Defendants' factor concentrate products were intentionally designed, manufactured, promoted, distributed and sold to be introduced into the human body.

PARAGRAPH NO. 92 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to another defendant, no response is required from Baxter. Baxter admits that the factor concentrate therapies which are the subject of this action are prescription biologics that are processed from human plasma as therapeutic agents for human beings. Baxter denies that factor concentrates are "products," or that they are "designed" or "manufactured." The remaining factual allegations directed to Baxter, if any, are denied.

93. Defendants breached the implied warranties of merchantability and fitness because Defendants' factor concentrate products cannot pass without objection in the trade, are unsafe, are not merchantable, are unfit for their ordinary use when sold, and are not adequately packaged and labeled.

PARAGRAPH NO. 93 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required from Baxter. Baxter denies that factor concentrates are "products." The remaining factual allegations directed to Baxter, if any, are denied.

94. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

PARAGRAPH NO. 94 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

Answer to Plaintiff's Negligence Allegations

95. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

PARAGRAPH NO. 95 ANSWER: Baxter incorporates by reference its responses to all preceding paragraphs as if fully set forth herein and further answers as follows:

96. Defendants marketed their Factor VIII and/or Factor IX blood products to and for the benefit of Plaintiff, and knew or should have known that Plaintiff would use their Factor VIII and/or Factor IX blood products.

PARAGRAPH NO. 96 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. Baxter specifically denies that Factor VIII or Factor IX are blood "products." The remaining factual allegations directed to Baxter, if any, are denied.

97. Defendants owed Plaintiff duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing best scientific knowledge.

PARAGRAPH NO. 97 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is

required. By way of further answer, Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

98. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, Defendants breached their duties to Plaintiff. The following sub-paragraphs summarize Defendants' breaches of duties to Plaintiff and describe categories of acts or omissions constituting breaches of duties by Defendants. Each and/or any of these acts or omissions establishes an independent basis for Defendants' liability in negligence:

a. Failure to exercise reasonable care in producing Factor VIII and Factor IX blood products that were free of viruses, including the virus that causes Hepatitis C;

b. Failure to exercise reasonable care in assuring that only suitable plasma would be used in manufacturing their Factor VIII and Factor IX blood products;

c. Failure to exercise reasonable care in testing plasma used in manufacturing their Factor VIII and Factor IX blood products for viral contamination;

d. Failure to exercise reasonable care in recruiting and screening donors of plasma used in their manufacture of Factor VIII and Factor IX blood products;

e. Failure to reasonably employ anti-viral techniques, including solvent and/or detergent treatment, in the manufacture of their Factor VIII and Factor IX blood products;

f. Unreasonable overpromotion of their Factor VIII and Factor IX blood products;

g. Understating the relative value of hemophilia treatments that constituted alternatives to their Factor VIII and Factor IX blood products;

h. Failure to warn physicians, Plaintiff, his guardians, and the hemophilia community of the dangers associated with their Factor VIII and Factor IX blood products and/or the viruses and foreign bodies contained within the plasma used in manufacturing their Factor VIII and Factor IX blood products;

i. Failure to exercise reasonable care by complying with federal regulations then applicable to plasma collection and the manufacture of Factor VIII and Factor IX blood products;

j. Failure to exercise reasonable care in disseminating information about their methods of manufacturing their Factor VIII and Factor IX blood products and the risks that were created by said methods; and

k. Failure to exercise reasonable care in recalling their Factor VIII and Factor IX blood products.

PARAGRAPH NO. 98 ANSWER: The allegations of this paragraph and all of its subparts constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. By way of further answer, Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

99. Defendants knew, or should have known, that, due to their failure to use reasonable care, Plaintiff and other people with hemophilia would use and did use Defendants' Factor VIII and/or Factor IX products to the detriment of their health, safety and well-being.

PARAGRAPH NO. 99 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

100. As the direct, proximate and legal result of the Defendants' negligence, Plaintiff has been injured and has incurred damages, including but not limited to physical injuries to his person, medical expenses in the past, past disability, past loss of use of the body, and past physical and mental pain and suffering; and may incur in the future medical and hospital expenses, permanent disability, loss of use of the body, physical and mental pain and suffering, and loss of the enjoyment of life.

PARAGRAPH NO. 100 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. Baxter

specifically denies that it was negligent or that Plaintiff was injured or suffered damages as a result of a wrongful act or omission by Baxter.

101. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

PARAGRAPH NO. 101 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required.

102. Defendants' conduct, as alleged above, was malicious, intentional and outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

PARAGRAPH NO. 102 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. Baxter specifically denies that its conduct was malicious, intentional, outrageous, willful or wanton or that Plaintiff was injured or suffered damages as a result of a wrongful act or omission by Baxter.

Answer to Plaintiff's Negligence Per Se Allegations

103. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

PARAGRAPH NO. 103 ANSWER: Baxter incorporates by reference its responses to all preceding paragraphs as if fully set forth herein and further answers as follows:

104. Defendants violated applicable federal statutes and regulations relating to prescription drugs. Plaintiff is a person whom these statutes and regulations were meant to protect.

PARAGRAPH NO. 104 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is

required. By way of further answer, Baxter states that it is without knowledge or information sufficient to form a belief as to the truth of any allegations regarding the identity of "Plaintiff" and therefore denies them. The remaining factual allegations directed to Baxter, if any, are denied.

105. Defendants' violation of these statutes or regulations constitutes negligence per se.

PARAGRAPH NO. 105 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required.

106. Defendants' violation of these statutes or regulations was the direct, proximate and legal cause of Plaintiff's injuries and damages. As the direct and legal result of the Defendants' negligence, Plaintiff has been injured and has incurred damages, including but not limited to physical injuries to his person, medical expenses in the past, past disability, past loss of use of the body, and past physical and mental pain and suffering; and may incur in the future medical and hospital expenses, permanent disability, loss of use of the body, physical and mental pain and suffering, and loss of the enjoyment of life.

PARAGRAPH NO. 106 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. By way of further answer, Baxter states that it is without knowledge or information sufficient to form a belief as to the truth of any allegations regarding Plaintiff's alleged injuries or damages and therefore denies them. The remaining factual allegations directed to Baxter, if any, are denied.

107. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

PARAGRAPH NO. 107 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required.

108. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

PARAGRAPH NO. 108 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. Baxter specifically denies that its conduct was malicious, intentional, outrageous, willful or wanton or that Plaintiff was injured or suffered damages as a result of a wrongful act or omission by Baxter.

WHEREFORE, Baxter Healthcare Corporation having fully answered, requests that this Court enter a judgment in its favor and against Plaintiff, and award Baxter its costs and expenses, including attorneys' fees in this matter, and grant such other relief as the Court may deem just and proper.

FIRST AFFIRMATIVE DEFENSE

Plaintiff's Complaint fails, in whole or in part, to state a claim against Baxter upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

The injuries and damages claimed by Plaintiff, if any, were caused by the negligence, fault, or other culpable conduct of persons other than Baxter and over whom Baxter had no control and for which matters Baxter bears no legal responsibility.

THIRD AFFIRMATIVE DEFENSE

At all relevant times, Baxter acted in conformity with the existing state of medical and scientific knowledge, common and accepted procedure in the medical field, and state of the art in the processing and distribution of factor concentrates.

FOURTH AFFIRMATIVE DEFENSE

The state of scientific and technical knowledge at the time when the therapy was put into circulation was not such as to enable Baxter to know the existence of the alleged defect, if any, or discover it.

FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitation and/or statutes of repose.

SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the learned intermediary doctrine.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the doctrines of laches, waiver and/or estoppel.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by doctrines concerning unavoidably unsafe therapeutics under the Restatement (Second) of Torts: Product Liability §402A and comments thereto and/or Restatement (Third) of Torts: Products Liability §6 and comments thereto.

NINTH AFFIRMATIVE DEFENSE

Some or all of Plaintiff's claims are barred or subject to reduction by the doctrines of contributory negligence or comparative fault. Accordingly, any recovery must be diminished to the extent of a finding of contributory negligence and/or comparative fault against him.

TENTH AFFIRMATIVE DEFENSE

Plaintiff and his guardians were warned of and/or assumed the risk, if any, related to the use of factor concentrates.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiff and his guardians, knowing the nature and properties of factor concentrates, consented to their use, and accordingly Baxter cannot be held liable.

TWELFTH AFFIRMATIVE DEFENSE

Baxter's factor concentrate is a prescription biologic which has been licensed and approved under 42 U.S.C. § 262 and the regulations issued thereunder. At all relevant times, Baxter's conduct was in compliance with the aforementioned statute and all other applicable federal statutes and regulations, including but not limited to the federal Food, Drug, and Cosmetic Act which preempt and bar the Plaintiff's claims, in whole or in part, by operation of the Supremacy Clause of the United States Constitution.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiff has failed to join parties necessary and/or indispensable to a just adjudication of this lawsuit.

FOURTEENTH AFFIRMATIVE DEFENSE

The alleged injuries of Plaintiff were the result of unavoidable circumstances, which could not have been prevented by anyone.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's injuries or damages, if any, were proximately caused by an intervening or superseding cause, and Plaintiff's recovery against Baxter is therefore barred.

SIXTEENTH AFFIRMATIVE DEFENSE

The Complaint fails to allege any cause of action which would entitle Plaintiff to exemplary or punitive damages under the applicable and/or governing law.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiff's demands for exemplary and punitive damages are barred because any award of such damages would violate the due process clauses of the Fifth and Fourteenth Amendments to the United States Constitution by allowing standardless discretion to the jury to determine punishment and by depriving Baxter of prior notice of the consequences of its alleged acts.

EIGHTEENTH AFFIRMATIVE DEFENSE

With respect to Plaintiff's demand for punitive damages, Baxter specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damages awards which arose in the decisions of BMW of North America v. Gore, 517 U.S. 559 (1996), Cooper Industries, Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001), State Farm Mut. Automobile Ins. Co. v. Campbell, 538 U.S. 408 (2003), and Philip Morris USA

v. Williams, 549 U.S. 346 (2007). To the extent Plaintiff's demand for punitive damages are governed by foreign law, punitive damages are not available to Plaintiff under applicable and/or governing law.

NINETEENTH AFFIRMATIVE DEFENSE

Punitive damages are a punishment, a quasi-criminal sanction for which Baxter has not been afforded the specific procedural safeguards prescribed in the Fifth and Sixth Amendments to the United States Constitution.

TWENTIETH AFFIRMATIVE DEFENSE

The Complaint fails to allege a cause of action that would entitle Plaintiff to attorneys' fees or costs.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff has failed to give timely notice of his breach of warranty claims, if any, and therefore is precluded from recovery.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred because they failed to mitigate damages.

TWENTY-THIRD AFFIRMATIVE DEFENSE

To the extent that Plaintiff's claims rest upon any theory that would allow a finding of liability without requiring proof of causation, they violate Baxter's rights under the United States Constitution, the Constitution of the State of Illinois and such other laws as may be applicable.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, pursuant to the doctrine of primary jurisdiction; the FDA is charged with regulating biologics, including factor concentrates, and is specifically charged with determining the content of the warnings and labeling for biologics.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to Buckman v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001).

TWENTY-SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff attempts to seek equitable relief, he is not entitled to such relief because he has an adequate remedy at law.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Some of Plaintiff's claims are barred in whole or in part by the First Amendment of the Constitution of the United States and/or the applicable Constitution or equivalent legal document of any state whose laws might be deemed controlling in this case.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Any recovery by Plaintiff must be reduced or offset by amounts Plaintiff has received or will receive from others for the same injuries claimed in this lawsuit.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred because Baxter did not owe them any legal duty or, if Baxter did owe such a legal duty, it did not breach that duty.

THIRTIETH AFFIRMATIVE DEFENSE

Damages for losses claimed by Plaintiff are limited by the California Medical Injury Compensation Reform Act (MICRA) including but not limited to California Code Sections 3333.1 and 3333.2, or other similar applicable statutes placing a cap on liability.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Some of the Plaintiff's alleged injuries or damages, if any, were the result of the misuse of factor concentrate.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part by the blood shield statutes of Illinois, or by the blood shield statutes of such other jurisdictions as may be applicable.

THIRTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims are barred or should be reduced under the doctrine of avoidable consequences due to Plaintiff's failure to mitigate damages.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's injuries and losses, if any, were proximately caused by his own acts or omissions and his claims are therefore barred.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's injuries and losses, if any, were proximately caused by his own failure to use factor concentrate in a reasonably foreseeable and intended manner, or in a manner consistent with the therapy's labeling and his claims are therefore barred.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

If it is determined that a risk is inherent in factor concentrate, then such risk is outweighed by the benefits of factor concentrates.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff relies upon the doctrine of failure to warn, he has failed to state a claim upon which relief can be granted.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred because there is no privity between Plaintiff and Baxter.

THIRTY-NINTH AFFIRMATIVE DEFENSE

Plaintiff's rights and claims against Baxter, if any, are barred in whole or in part by public policy considerations.

FORTIETH AFFIRMATIVE DEFENSE

No implied warranties of fitness for a particular purpose, or for merchantability, existed with respect to any transaction alleged to have been entered by Baxter, or in the alternative, such warranty or cause of action based upon such warranty was waived by Plaintiff.

FORTY-FIRST AFFIRMATIVE DEFENSE

Any condition in question alleged to have constituted a breach of implied warranties by Baxter was not a proximate cause of Plaintiff's alleged injuries or damages.

FORTY-SECOND AFFIRMATIVE DEFENSE

Some or all of Plaintiff's claims are barred, in whole or in part, by the doctrines of *res judicata*, and/or satisfaction and accord.

FORTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims are barred to the extent they seek to impose liability retroactively for conduct that was not actionable at the time it occurred.

FORTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's and his counsel have vexatiously and unreasonably pursued this action and Baxter is therefore entitled to costs, expenses and attorneys' fees reasonably incurred because of such conduct.

FORTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by the doctrine of lis pendens.

FORTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by settlement of their claims.

FORTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's claims fail, in whole or in part, because of improper claim splitting.

FORTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiff may not recover on the claims pleaded in the Complaint because the damages sought are too speculative and remote.

FORTY-NINTH AFFIRMATIVE DEFENSE

Plaintiff's claims for relief, on their face and as applied, violate the Excessive Fines Clause of the United States Constitution, and/or the applicable Constitution or equivalent legal document of any state whose laws might be deemed controlling in this case.

FIFTIETH AFFIRMATIVE DEFENSE

While denying at all times that factor concentrates processed by Baxter caused or contributed to the injuries and damages alleged in the Complaint, Baxter avers that Plaintiff was warned or otherwise made aware of the alleged risks and further, that any such risks, to the extent they existed, were not beyond those that would have been contemplated by an ordinary user. Plaintiff, therefore, is barred from any recovery on the claims asserted.

FIFTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's fraud and misrepresentation claims cannot be sustained because Baxter did not have superior knowledge of material facts that were not also readily available to Plaintiff and Plaintiff has failed to plead such claims with particularity.

FIFTY-SECOND AFFIRMATIVE DEFENSE

This Court is neither a proper nor convenient forum for the just adjudication of Plaintiff's claims.

FIFTY-THIRD AFFIRMATIVE DEFENSE

Any affirmative defenses pleaded by the other Defendants and not pleaded by Baxter are hereby incorporated herein to the extent they do not conflict with Baxter's affirmative defenses.

FIFTY-FOURTH AFFIRMATIVE DEFENSE

Baxter hereby gives notice that it intends to rely upon any other defense that may become available or appear during the discovery proceedings in this case and hereby reserves the right to amend its Answer to assert such defenses.

FIFTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims may fail due to lack of jurisdiction.

FIFTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claims are improperly joined and should be dismissed.

WHEREFORE, Baxter Healthcare Corporation having fully answered, requests that this Court enter a judgment in its favor and against Plaintiff, and award Baxter its costs and expenses, including attorneys' fees in this matter, and grant such other relief as the Court may deem just and proper.

DATED: August 22, 2008

s/RICHARD L. BERKMAN
Richard L. Berkman
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104-2857
215-994-4000 (phone)
215-994-2222 (fax)

Attorney for Defendant
Baxter Healthcare Corporation

DEMAND FOR JURY TRIAL

Defendant Baxter Healthcare Corporation demands a trial by jury on all issues stated.

Dated: August 22, 2008

s/ RICHARD L. BERKMAN
Richard L. Berkman
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104-2857
215-994-4000 (phone)
215-994-2222 (fax)

Attorney for Defendant
Baxter Healthcare Corporation

CERTIFICATE OF SERVICE

I hereby certify that on this 22nd day of August, 2008, that I caused to be served a true and correct copy of Baxter Healthcare Corporation's Answer to Plaintiff's Complaint, Affirmative Defenses, and Demand for Jury Trial upon the following counsel of record pursuant to ECF as to Filing Users and by DHL delivery, postage prepaid, pursuant to Local Rule 5.5 as to any party who is not a Filing User or represented by a filing user:

Heather A. Foster
LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP
275 Battery Street
30th Floor Embarcedero Ctr. West
San Francisco, CA 94111-3339

Sheldon J. Schlesinger
John Uustal
SHELDON J. SCHLESINGER, P.A.
1212 Southeast Third Avenue
Fort Lauderdale, FL 33316

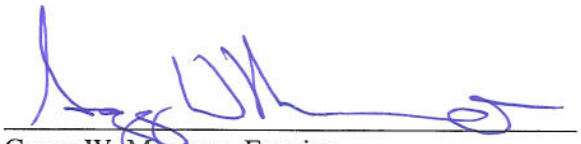
Paulina do Amaral
LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP
780 Third Ave 48th Fl
New York, NY 10017

Robert J Weltchek
SNYDER WELTCHEK AND SNYDER
1829 Reisterstown Rd Ste 100
Baltimore, MD 21208

Kevin Stack
KNAPP, PETERSEN & CLARKE
500 North Brand Boulevard, 20th Floor
Glendale, CA 91203

Kasper Stoffelmayr
BARTLIT, BECK, HERMAN, PALENCHAR & SCOTT, LLP
1899 Wynkoop Street
Denver, CO 80202

Duncan Barr
O'CONNOR, COHN, DILLON & BARR
2405 16th Street
San Francisco, CA 94103-4210



Gregg W. Marsano, Esquire